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APPENDIX 8

DEVELOPING SPONSORED RESEARCH AGREEMENTS: CONSIDERATIONS FOR RECIPIENTS
OF NIH RESEARCH GRANTS AND CONTRACTS

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The following is a reprint of the Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research and Contracts, which was published in the Federal Register of June 27, 1994.

INTRODUCTION

The National Institutes of Health (NIH) is the principal biomedical and behavioral research agency within the Federal Government. Its mission is to improve human health by increasing scientific knowledge related to health and disease through the conduct and support of biomedical and behavioral research. The NIH advances its mission through intramural research activity and the award of research grants and contracts to institutions of higher education, research institutes and foundations, and other non-profit and for-profit organizations. Entities funded through NIH research grants,

contracts, and cooperative agreements (hereafter collectively referred to as Grantees) are required to maximize the use of their research findings by making them available to the research community and the public at large and through their timely and effective transfer to industry for development.

In general, interactions between Grantees and industry take many forms, including industrial liaison programs, spinoff companies, consortia, commercial licenses, material transfers, consultations, and clinical trial agreements. This document addresses one form of Grantee/industry interaction, sponsored research agreements, on which the NIH has focused a substantial amount of its recent attention. Sponsored research agreements are agreements between Grantees and commercial entities in which Grantees receive funding or other consideration to support their research in return for preferential access and/or rights to intellectual property deriving from their research results.

In developing sponsored research agreements, Grantees must consider the Bayh-Dole Act of 1980 (1) (hereafter referred to as "Bayh-Dole" or "the Act") and NIH funding agreements and refrain from engaging in activities which undermine a Grantee's ability to fulfill its responsibilities and obligations to the Federal government. Although Grantees are primarily responsible for the implementation of the Act, NIH, as a steward of Federal funds, has a responsibility to provide guidance on issues regarding sponsored research agreements which may put Grantees at odds with the Act or NIH funding requirements.

PURPOSE

The purpose of this document is to provide Grantees with issues and points to consider in developing sponsored research agreements with commercial entities. The intent is to assist Grantees in ensuring that those agreements comply with the requirements of the Act and NIH funding agreements while upholding basic principles of academic freedom.

This document represents the culmination of various activities, under the aegis of the NIH Task Force on Commercialization of Intellectual Property Rights from NIH Supported Extramural Research, which included the review and analysis of 375 sponsored research agreements from 100 Grantees, meetings with industry, academia, and other Government agencies, and a specially convened public forum involving subject matter experts from outside of the NIH.

The NIH recognizes that sponsored research agreements are unique, creative devices which reflect the needs and interests of the parties involved and require a delicate balance of risks and benefits to all of the parties. Although this document identifies a number of points to consider, with some necessitating more scrutiny than others, no single point or issue is so dominant that it is likely to be fatal to an agreement. Rather, the juxtaposition of multiple factors or clauses in an agreement and their synergy needs to be assessed. Therefore, Grantees should review the provisions of proposed sponsored research agreements both individually and in their totality.

BACKGROUND

While NIH policies on the use of research results have been in effect for some time, commercial development of research results took a major step forward with the passage of the Bayh-Dole Act. Congress passed the Act in response to significant concerns about the United States' competitiveness and data indicating that rights to many inventions developed under Federal grants and contracts and assigned to the Federal government were not being commercialized. In general, the Act authorizes Grantees to retain title to inventions resulting from their Federally funded research and to license such inventions to commercial entities for development.

Specifically, the policy and objective of the Bayh-Dole are to:

- o Promote collaboration between commercial concerns and nonprofit organizations, including universities;
- o Promote the utilization of inventions arising from Federally supported research or development;
- o Encourage maximum participation of small business firms in Federally sponsored research and development efforts;
- o Ensure that inventions made by nonprofit organizations and small business firms are used to promote free competition and enterprise;
- o Promote the commercialization and public availability of inventions made in the United States by United States industry and labor;
- o Ensure that the Government obtains sufficient rights in Federally sponsored inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and

- o Minimize the costs of administering policies in this area.

The provisions of the Act have been implemented through regulations issued by the Department of Commerce and adopted by the Department of Health and Human Services.(2)

The Act serves the public not only by encouraging the development of useful commercial products such as drugs and clinical diagnostic materials, but also by providing economic benefits, and enhancing U.S. competitiveness in the global market place.

Since its passage, the Bayh-Dole Act has been effective in promoting the transfer of technology from Grantees to industry as evidenced by the aggressive pursuit of patenting and licensing and the proliferation of university/industry collaborations (3). In addition, the development of many new and important drugs and devices have been facilitated by increased industrial support for academic research (4) and the explosion in the licensing of university owned inventions (5). Furthermore, statistics indicate that the Act has provided significant economic benefits which are projected as increasing between 25 to 30 percent per year (6).

GRANTEE RESPONSIBILITIES

In keeping with the objectives and policy of Bayh-Dole, it is incumbent upon Grantees to effectively and efficiently transfer technology to industry for commercial development. However, in doing so Grantees must also comply with the specific terms of the Act, its

implementing regulations, and the terms and conditions of each NIH award and ensure that such compliance is reflected in their agreements with commercial entities.

In carrying out that responsibility, at a minimum, Grantees need to concern themselves with issues involving maintenance of academic freedom for institutions and investigators, fair access to information, timeliness of notification and other requirements, rational licensing to commercial entities, and adherence to the specific requirements of the Act and NIH funding agreements.

While sponsored research agreements frequently are used where basic research is involved and no invention exists to disclose nor intellectual property to license at the time the agreement is executed, Grantees should anticipate such issues to arise and use the following points for consideration in developing a sponsored research agreement.

The first section, Universal Points for Consideration, highlights several requirements and issues that Grantees should consider in all proposed sponsored research agreements. The second section, Points for Special Consideration, delineates circumstances which suggest heightened scrutiny. The third section, Other Points for Consideration by Non Profit Grantees, contains additional considerations which apply only to non profit Grantees.

UNIVERSAL POINTS FOR CONSIDERATION

Academic Freedom

Academic research freedom based upon social collaboration within the scientific community and the scrutiny of claims and beliefs by its members is at the heart of scientific advancement within the United States. Primarily through Federal funding, academic institutions have contributed to fundamental knowledge and techniques upon which current and future scientific discoveries and technological innovations depend. Therefore, the preservation of academic freedom for Grantee institutions and researchers is of considerable concern to the NIH.

Grantees should be aware that their interest in the scientific endeavor covered by a sponsored research agreement and the interest of the industrial sponsor may not be totally consonant. As a result, in general, Grantees should ensure that sponsored research agreements preserve the freedom for academic researchers to select projects, collaborate with other scientists, determine the types of sponsored research activities in which they wish to participate, and communicate their research findings at meetings, and by publication and through other means (7). Academic researchers also should be made aware of any agreements executed by their institutions which may restrict their ability to pursue research activities and publish research results. Grantees also should maintain their independence to pursue their own mission without undue influence or restraint by their industrial sponsors. For example, an agreement which gives an industrial sponsor the ability to direct the research mission of a Grantee would be inappropriate.

Dissemination of Research Results

Grantees must ensure that the timely dissemination of research findings is not adversely affected by the conditions of a sponsored research agreement. For example, the PHS Grants Policy Statement, incorporated as a condition of each NIH research grant, details policies on publication of research results, responsibilities to disseminate information on unique research resources, and standards of conduct for Grantee employees. Although an industrial sponsor's consideration of the commercial applicability of specific research findings and/or the filing of a patent application to secure intellectual property rights may justify a need to delay disclosure of research findings, a delay of up to thirty (30) days is generally viewed as a reasonable period for such activity. Depending upon the individual circumstances, Grantees could consider a shorter or longer period of time, as they deem appropriate. In addition to the timing, a sponsored research agreement which requires the disclosure of inventions and research findings developed with NIH funds to an industrial sponsor prior to submission of the invention disclosure to the NIH, may be inconsistent with the terms and conditions of the NIH grant or contract.

Utilization

The NIH also has a concern that Federally funded technology be developed and commercialized in an expedited and efficient manner. In deciding to enter into an agreement with an commercial entity, Grantees should consider whether the organization has the experience, capability, and commitment to bring its likely inventions to commercial status.

Additionally, Grantees should not enter into sponsored research

agreements that permit a sponsor to tie up the development of a technology by acquiring exclusive licensing rights to the product of given research results before deciding whether or not it will actively develop and commercialize that product. Grantees should provide a sponsor with an option to pursue licensing rights. It is reasonable for such options to be limited to no more than six (6) months. However, individual circumstances may dictate a shorter or longer period of time. After the option period expires, the technology should become available for licensing to other entities. Moreover, once a sponsor decides not to exercise its option, it should not be given a second opportunity to obtain licensing rights by matching other parties' offers for the rights. Such requirements enable Grantees to license to companies presenting a bona fide commercialization plan, thus expediting the availability of products to the public.

In order to ensure that technology is developed rapidly and is not being subjected to delays, Grantees should also establish, maintain, and actively administer policies and procedures which ensure that licenses arising from sponsored research agreements contain due diligence requirements and benchmarks to monitor performance. When future rights to as yet undiscovered inventions are included in a sponsored research agreement, benchmarks for development of each such invention should be established as it becomes available for commercial development. In addition, Grantees should actively monitor licensees in accordance with those requirements and benchmarks to assure compliance with Grantee obligations under the Act.

U.S. Manufacture

The Bayh-Dole Act requires that products developed with Federal funds and used and sold in the United States, be substantially manufactured here. In granting exclusive rights to use or sell any subject invention in the United States, Grantees must ensure that each agreement requires that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. In individual cases, a request for waiver may be considered by the NIH. A determination will be made based upon a showing by the Grantee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. In granting a waiver of the U.S. manufacture requirement, the NIH may consider other benefits conferred on the United States by the potential license including the rapid availability of a product of benefit to the health of the American people.

Notification Requirements and Records

In sponsored research agreements, as in other contexts, Grantees must also ensure that invention, patent and license notification requirements are adhered to in a timely manner. Timeliness considerations include prompt (1) employee notification to Grantee administrators of an invention made under NIH funding, (2) written disclosure to NIH of an invention and the intent to retain or convey to the Government title to the invention, (3) adherence to time frames for initial filing of patent applications in the United States

and the filing of foreign patent applications, (4) execution and confirmation throughout the world of NIH license rights in the results of the research, and (5) notification to the NIH of any decision not to continue patent prosecution, pay fees, or defend the patent in reexamination.

Specifically, as conditions of NIH grants and cooperative agreements, Grantees must fully notify the NIH in a timely manner when an invention has been developed. In any event, disclosure to the NIH must be prior to the publication of any description of the invention. When applying for continued funding in each subsequent funding period, the institution must also provide either a listing of all inventions made during the preceding budget period or a certification that no inventions were made during the applicable period. A final invention statement and certification listing all inventions that were conceived or first actually reduced to practice during the course of work under the funding agreement is required within ninety (90) days following the expiration or termination of support on an applicable project. Additionally, Grantees need to adhere to the specific requirements contained in the patent clauses of their contracts as well as the general provisions of the Federal Acquisition Regulations.

Furthermore, Grantees must also document their compliance with the requirements of the Act, regulations, and terms and conditions of NIH awards, generally and as related to sponsored research agreements. Such Grantee records must be available for review by authorized Federal officials in accordance with the terms and conditions of the

award. For example, concerning access and retention of records under NIH grants and cooperative agreements, regulations require grantees to retain financial and programmatic records, supporting documents, statistical records, and all other grantee records which may reasonably be considered pertinent to a grant or subgrant (8).

POINTS FOR SPECIAL CONSIDERATION

The NIH has identified several situations, outlined below, in which Grantees should exercise heightened sensitivity and scrutiny in the development of sponsored research agreements. Such an exercise should confirm that a sponsored research agreement does not adversely impact NIH funded activities and Grantee concerns such as academic freedom, or shift control of the Grantee's scientific activities, management, and independence into the hands of the sponsor. While there is no requirement that Grantees submit proposed sponsored research agreements to the NIH for review, at the discretion of the Grantee, the NIH may be consulted for additional clarification in instances where special considerations warrant.

First, Grantees should subject their sponsored research agreements to heightened scrutiny when one or more of the following threshold criteria apply:

(a) the amount of financial support from the sponsor meets or exceeds \$5 million in any one year, or, \$50 million total over the total period of funding under the agreement;

(b) the proportion of funding by the sponsor exceeds 20 per cent of

the Grantee's total research funding;

(c) the sponsor's prospective licensing rights cover all technologies developed by a major group or component of the Grantee organization, such as a large laboratory, department or center, or the technologies in question represent a substantial proportion of the anticipated intellectual output of the Grantee's research staff; or

(d) the duration of the agreement is for 5 or more years.

If one or more of these criteria apply, it is more likely that the proposed sponsored research agreement will adversely affect open commercial access, especially for small businesses, to a Grantee's Federally funded research activities and may delay or impede the rapid development and commercialization of technology.

Second, Grantees should be concerned if the scope of the sponsored research agreement is so broad that the subsequent exclusive licensing of technology under the agreement provides a single sponsor with access to a wide array of Grantee research findings and technologies that effectively exclude other organizations from reasonable access to a Grantee's technology. This type of arrangement can also delay commercialization if the sponsor does not have the interest or the capability to develop the technology.

Third, if the sponsor contributes funds to support a Grantee's general operations rather than specifically defined research projects, the Grantee should consider the amount of the sponsor's

general funding in relation to funds contributed from other sources when determining what prospective intellectual property rights the (sponsor will receive in the results of the Grantee's entire research portfolio. There should be a reasonable relationship between the amount of money contributed by the sponsor and the rights that it is granted both to review and license resulting technology or inventions. As an extreme example, a sponsor should not be able to provide 5 percent of the Grantee's total support, review 100 percent of the Grantee's inventions, and receive rights or a first option to 50 percent of the research results generated by the Grantee. Where general funding is involved, a Grantee should consider establishing some mechanism to limit the review and licensing rights of the sponsor to a particular segment or percentage of the inventions and for a set period of time. For example, the Grantee may require the sponsor to select those research areas or projects to which its general funding rights would attach in advance, thereby freeing up research areas that may be of interest to other commercial entities. Because, by its nature, general funding is less directed and its results more imprecise, Grantees should carefully monitor the impact on open competition and fair access by small business of the sponsor's licensing practices for technology supported by general funding.

Fourth, Grantees should avoid any other unusual practice or stipulation that might generate public concern or undermine rather than serve the public interest.

OTHER POINTS FOR CONSIDERATION BY NON-PROFIT GRANTEES

The following points are to aid non-profit Grantees in administering the Act and in complying with the requirements of NIH funding agreements.

First, Grantees must ensure that the rights to inventions resulting from Federal funding are not assigned without NIH approval. An exception to this is when the assignment is made to an organization which has as one of its primary functions the management of inventions, in which case, the assignee will be subject to the same provisions as the Grantee.

Second, Grantees must share royalties collected on NIH supported inventions with the inventors and the balance of any royalties or income earned, after payment of expenses, including payment to inventors and incidental expenses to the administration of subject inventions, must be utilized for the support of scientific research or education.

Third, Grantees must employ reasonable efforts to attract licensees of subject inventions that are small business firms. Additionally, Grantees must provide a preference to small business firms when licensing a subject invention if Grantees determine that small business firms have plans or proposals for marketing the invention which, if executed, are equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms. However, Grantees must be satisfied that the small business firms have the capability and resources to carry out plans or proposals. The decision whether to give a

preference in any specific case is at the discretion of the Grantee. However, since sponsored research agreements typically provide exclusive licenses or options to such rights to the sponsor, Grantees should seriously consider and provide for these issues when negotiating such agreements.

CONCLUSION

Technology transfer is a vehicle through which the fruits of NIH funded research are transferred to industry to be ultimately developed into preventive, diagnostic and therapeutic products to advance human health. In a dynamic and multinational marketplace, if the United States is to remain a world leader in technological and scientific innovation, both the public and private sectors must work together to foster rapid development and commercialization of useful products to benefit human health, stimulate the economy, and enhance our international competitiveness, while at the same time protecting taxpayers' investment and safeguarding the principles of scientific integrity and academic freedom.

It is in this spirit that the NIH encourages Grantees to address the issues and apply the points for consideration identified in this document when developing sponsored research agreements with commercial entities.

INQUIRIES

Comments or inquiries may be directed to:

Mr. Theodore J. Roumel

Office of Science Policy and Technology Transfer

National Institutes of Health

6011 Executive Boulevard, Suite 325

Rockville, MD 20852-3804

Telephone: (301) 496-7057 ext. 203

FAX: (301) 402-0220

FOOTNOTES

1. Public Law 96-517, enacted December 12, 1980, Chapter 38--Patent Rights in Inventions Made with Federal Assistance.

2. The Department of Commerce regulations are at 37 Code of Federal Regulations (CFR) Part 401 and supersede applicable portions of 45 CFR Parts 6 and 8.

3. Approximately one in every four university patents issued in the late 1980s was for a biomedical or health related invention. In the early 1970s, the ratio was one in eight. Source: Science and Engineering Indicators, 1993, National Science Foundation.

4. While still representing less than 10 percent of the total funding for academic research, it is estimated that nearly two percent of United States industry's expenditures for R&D now goes to academic institutions, as compared with less than 1 percent in 1971. Source: Science and Engineering Indicators, 1993, National Science Foundation.

5. Over 1000 licenses or options were executed in Fiscal Year 1992 by 260 academic institutions surveyed. The institutions also reported that they had over 5000 active licenses in place at the time of the survey. Source: Association of University Transfer Managers Licensing Survey FY 1991-1992, published October, 1993.

6. In FY 1992 sales and employment attributable to the Act were estimated to be as follows: between \$9 and \$13 billion in sales and 50-100,000 jobs, with an annual increase of between 25 and 30 percent. Source: Dr. Ashley J. Stevens, Director, Office of Technology Transfer, Dana-Farber Cancer Institute, Association of University Technology Managers Winter Meeting, 1994.

7. The NIH recognizes that there may be certain instances when it may be reasonable for a Grantee institution to agree to minimally restrict a researcher from collaborating with another industrial partner when the subject matter of such collaboration overlaps with that of the sponsored research agreement.

8. The regulations are set forth at 45 CFR Part 74, Subpart D and 45 CFR Part 92.42.

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892